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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,527	03/30/2004	Alpern Robert	RLY 04021.101	6886

58415 7590 11/12/2008

SENNIGER POWERS LLP (ILPS)
100 NORTH BROADWAY
17TH FLOOR
ST. LOUIS, MO 63102

EXAMINER	
LEVY, NEIL S	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
11/12/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary	Application No.	Applicant(s)	
	10/814,527	ROBERT ET AL.	
	Examiner	Art Unit	
	NEIL LEVY	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-11,13-16,36-51,60 and 61* is/are pending in the application.

4a) Of the above claim(s) *3,5-11,45-48,50 and 51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,13-15,36-44,60 and 61* is/are rejected.

7)☐ Claim(s) *16* is/are objected to.

8)☒ Claim(s) *1,3,5-11,13-16,36-51,60 and 61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim3, 5-11, 45-48,50,51 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species , there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/2/07.

Claim Rejections - 35 USC § 112

Claim 1, 13-15, 36—44,60,61 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administering an acid resin to dogs and rats with compromised kidney function, does not reasonably provide a basis for identification of an effective amount, for a given species, age, sex, of acid resin to give, for any period of time, to any human or specific animal with any of the claimed diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to Practice the invention commensurate in scope with these claims.

The human model studies are written as prophetic, intended studies; no results are evident. Applicant presumes beneficial results will be achieved in hypertension, cirrhosis, edema, pre-eclampsia, pregnancy, acidosis, heart failure and other conditions of fluid overload, permitting reduction of dialysis, calcium channel blockers, and other drugs. The specification presents no basis for the practitioner to know that any administered acid resin in any amount will in fact result in amelioration of any of the claimed conditions. Extensive experimentation, inclusive of the use of models would be needed to identify if any of the claimed results could be obtained.

The data regarding sodium binding is human-based, thus it is not evident that doses based on this data would provide, in the undiscernibly identifiable "animal in need " could be determined to be effective for any of the syndromes claimed, without extensive

experimentation. One can not determine if any given claimed syndromes, doses, & benefits apply to a particular animal or

to human.The specification is not seen as equally descriptive of each of the claimed elements, without regard to the particular animal species, or a human.

We see no support claim 36, 39 end stage renal, cirrhosis, chronic renal insufficiency or fluid overload, nor for PREVENTION of edema @ claim 41, 60, 61, or for claim 42. . claim 43 in particular is not supported as to which animal, or human, would be treated with the specified drugs.

Only the claimed polymer of claim 16 and moeities of 1, in human subjects, rats and dogs, have been shown to be able to remove sodium. No indication exists to suggest a total removal of excess sodium, resulting in prevention, as in claim 41.

The claim 13 acid resin (now – sodium binding polymer) must have both H or NH4 and moeities of claim 1.

Claim Rejections - 35 USC § 103

Claims1,13 -15,36-44,60 & 61 stand rejected under 35 U.S.C. 103(a) as being unpatentable over MARTANI EP 039453 IN VIEW OF MURUGESAN et al US005846990A & NOTENBOMER EP 0730494

MARTANI utilizes eudrajit polymers with added actives. As they travel through the GI tract, and release active, the carboxylic moeities of the eudrajit polymer would be free to bind Na, at the same positions of the GI tract and to the same degree, as would administration of the instant polymers. However, MARTANI discusses the oral

formulations, but not the disease states. Those are shown by MURUGESAN, with associated drugs, to be administered, orally, in any suitable manner to humans and animals (column 8, lines 38-46), thus, inclusive of bound to polymers taught by MARTANI.

The same moeities are seen on the NOTENBONER polymer, and they do in fact lower sodium ion levels and water in human and animals (column 4, lines 1-9) when applied in food, feed, drinks, or pharmaceutical compositions.

Martani, applicant's arguments notwithstanding shows a laxative, glycerin (examples 2,3) with acrylic acid & polystyrene sulfonate acid resins, for oral administration to patients in pain, regardless of their disease(p.3, lines 9-18). Since these dosages are oral, they would remove Na as they pass through the G.I. tract, since these are the instant polymers.

MURUGESAN further shows the instant syndromes for which the instant drugs (claim 43) are suitable , & thus treatment regimens of MARTANI would be obvious to incorporate with useful drugs of MURUGESAN (col. 7).

Notenbomer discloses a particle formulation comprising a cation exchange resin with the claimed moietys, able to bind sodium ions (page 3, lines 3-20). Page 3, lines 8-12 teaches that the particles encapsulate the ions and remove them through the GI tract. Page 3, lines 20-34 discloses examples of the cation exchange material such as polyacrylates. Page 4, lines 1-2 teach that the particles of the invention are good for lowering Na, thus supporting administration of these polymers would result in reducing Na load in a patient in need there of.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize a Na binding polymer to use one of MARATANI modified with MURUGESAN & Notenbomer drugs, in order to provide acceptable application and improve the status of a patient in need there of.

There is no unobvious and/or unexpected results obtained since the prior art is well aware of the use of cation exchange polymerfs for enhancement and the use of ingredients for the functionality for which they are known to be used is not a basis for patentability.

Applicant has not provided any objective evidence of criticality, nonobvious or unexpected results that the administration of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed.

Double Patenting

Claim1, 36-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1, 5, 8-17, 30 of copending Application No10/965274. Although the conflicting claims are not identical, they are not patentably distinct from each other because 965 would anticipate the instant claim, as the same acid resins are administered.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1,13-14,36-43,60,61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim43-49,52-59,61-64 of copending Application No. 11/096209. Although the conflicting claims are not identical, they are not patentably distinct from each other because Since the same resins are administered , the same effects would result, cation, including Na, binding...

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed 8/20/08 have been fully considered but they are not persuasive. Applicant argues undue experimentation is not necessary to determine the calim limitations. For example, cardiac diseases in which it is claimed that sodium removal by sufficient amount of the various moeities of unspecified polymers, resulting in prevention of edema after cardiac event, would follow oral administration. We find the concept hopeful, but not dependably certain of success.

As to the obviousness rejection, applicant argues the references do not show a basis for combination, and argue that that animal results are unpredictable (apge 5, top). Further, MARTANI does not discuss the instant diseases and MURUGERSAN is for small molecues. Applicant relies on the polystyrene polymers of the references. However, all show acrylic polymers, too, and combination with actives is shown by MURUGERSAN, thus useful with actives of MURTANI, with end results of sodium-binding and removal as expressed by NOTENBONER.. The double patenting rejection is maintained. Rejoinder is not appropriate as rejections of the elected species are maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NEIL LEVY/
Primary Examiner, Art Unit 1615

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